REMARKS

Claims 30-45 and 47 are pending in the subject application. By this amendment applicant has canceled claim 46 without disclaimer or prejudice to applicant's right to pursue the subject matter of this claim in the future. In addition, applicant has amended claims 30 and 47. Support for the amendments to claim 30 may be found in the specification at, inter alia, page 22, lines 14-16. Claim 47 has been amended to correct its dependency.

Claims Rejected Under 35 U.S.C. §103(a)

Claims 30-40 and 42-47

In the March 23, 2007 Office Action, the Examiner rejected claims 30-40 and 42-47 under 35 U.S.C. §103(a) as allegedly obvious over Berger (U.S. Patent No. 6,090,799) in view of Schafer (U.S. Patent No. 4,456,596).

In response, applicant respectfully traverses the Examiner's rejection. However, in order to expedite prosecution and without conceding the correctness of the Examiner's position, applicant has hereinabove amended claim 30, from which the remaining rejected claims depend.

Unexpected Results

The invention as now claimed is a method of promoting weight gain after weight loss resulting from post-burn catabolism in a patient wherein, inter alia, the weight gained is maintained at five weeks after discontinuation of oxandrolone

administration. Berger does not teach or suggest maintenance of weight gain after discontinuation of oxandrolone administration. In fact, in the example given in Berger (see Col. 8, lines 19-22) "weight loss ensued" in the HIV-seropositive patient when unable to continue oxandrolone therapy. Thus the expectation from the prior art is weight loss after discontinuation of oxandrolone. The remaining cited art, in combination with Berger, does not alter this expectation. Moreover, the specification at page 22, lines 20-24 notes that muscle gain in body builders caused by anabolic agents "diminishes with the discontinuation of the drug" and contrasts this to the maintenance of weight observed with oxandrolone in burn victims. Accordingly, although the expectation from the art is of weight loss after discontinuation of oxandrolone, the claimed method is one showing maintenance of weight gained after discontinuation of oxandrolone. Thus, the method of promoting weight gain after weight loss resulting from post-burn catabolism as claimed possesses an unexpected and superior characteristic rendering it not obvious over the prior art.

Secondary Considerations

Long felt-need: Weight loss in burn victims has been long-recognized problem (for example, since at least 1973, see **Exhibits A-C**) and treating it has long been a therapy goal (see **Exhibits A-C**). In addition, oxandrolone had been available since 1964 and was known, as an anabolic steroid, to have growth effects. However, not until applicant's invention was oxandrolone used to treat weight loss in burn victims, i.e. more than twenty years after it had been established that

weight loss in burn victims should be treated and it was known that oxandrolone was anabolic. Accordingly, absent impermissible hindsight, it is not reasonable to assert that the claimed method was "obvious" when those skilled in the art had apparently failed to find it obvious for over twenty years.

Differences with Prior Art

In their previous response, applicant pointed out that because of different etiologies of weight loss in subjects with HIV myopathy as compared to burn victims, it was not predictable that just because oxandrolone increased weight in a subject with HIV-mypoathy that oxandrolone would also increase weight in a subject who had suffered post-burn catabolism.

The Examiner responded that Berger teaches that oxandrolone attenuates loss in muscle mass (wasting) and reverses weight loss. Applicant does not disagree with the Examiner's statement except for the Examiner's implication that it applies to any weight loss situation other than HIV-myopathy. In fact, the text quoted by the Examiner comes from the "Summary of the Invention" and states, in full:

> "The present invention provides a method which employs oxandrolone (an anabolic steroid with weak androgenic activity) as an alternative approach to the clinical management of HIV-associated myopathy/muscle weakness/muscle wasting. Loss in muscle mass (wasting) is attenuated, and body weight can be more readily maintained in this manner. Such an approach has been applied successfully to improve strength, reverse weight loss, and provide an improved sense of well-being."

Thus, Berger teaches oxandrolone administration reverses weight loss in subjects with HIV-associated myopathy. Applicant maintains that because of different etiologies of weight loss in HIV myopathies as compared to burns victims (including hypermetabolism in burn victims) it was not predictable that just because oxandrolone increased weight in a subject with HIV-myopathy then it would also increase weight in a subject who had suffered post-burn catabolism. As applicant previously pointed out, weight gain will only occur if the increase exceeds the decrease, and the multiple causes of weight loss in burn victims, including tissue loss and hypermetabolism as well as increased metabolic rate, would render this unpredictable.

Claims 30 and 41

The Examiner also rejected claims 30 and 41 under 35 U.S.C. §103(a) as allegedly obvious over Berger, as cited, in view of Schafer, as cited, and in further view of Labrie et al. (U.S. Patent No. 5,434,146). The Examiner indicated that the teachings of Berger and Schafer are as indicated above, but that Berger does not teach the administration of oxandrolone in a sustained release formulation. The Examiner further asserted that Labrie et al. teach the administration of oxandrolone in a sustained release formulation. The Examiner alleged that in view of this it would have been prima facie obvious to one of ordinary skill in the art that the administration of an effective amount of oxandrolone in a sustained release formulation would be effective for promoting

weight gain after weight loss resulting from post-burn catabolism.

Applicant notes that, as set forth hereinabove, there is no teaching of the method of claim 30 in the combination of Berger and Schafer, and Labrie et al. does not cure this deficiency. In fact Labrie et al. does not teach weight gain therapies or subjects that have experienced a burn, but instead teaches treatment and prevention of estrogen-related diseases (see Abstract and Summary of Invention). The Examiner does assert that the Labrie et al. discloses administration of oxandrolone in a sustained release formulation. To the extent that Labrie et al. may teach a sustained release composition, it still does not teach a method of administration of oxandrolone to a patient for treating weight loss resulting from post-burn catabolism wherein the weight gained is maintained at five weeks after discontinuation of oxandrolone administration. Nor does it cure the other deficiencies of the combination of Berger and Schafer. Applicant maintains that the cited combined references do not teach or make obvious applicant's invention as claimed.

Summary

Thus, applicant maintains that claims 30-45 and 47 as amended are not obvious over the combination of cited references. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw these grounds of rejection.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with his duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following items which are listed on the Form PTO-1449 (Substitute) attached hereto as **Exhibit D** and are also listed below. Copies of items 1-6 are attached hereto as **Exhibits 1-6**, respectively.

1. Larkin, J.M. and Moylan, J.A. (1976) "Complete enteral support of thermally injured patients." Am J Surg., 131(6):722-4 (Abstract) **(Exhibit 1)**;

2. Curreri, P.W. and Luterman, A. (1978) "Nutritional support of the burned patient." Surg Clin North Am., 58(6):1151-6 (Abstract) **(Exhibit 2)**;

3. Newsome, T.W., et al. (1973) "Weight Loss Following Thermal Injury." Ann. Surg., 178(2):215-217 **(Exhibit 3)**;

4. October 5, 2007 Final Office Action issued in connection with U.S. Serial No. 10/799,264 **(Exhibit 4)**;

5. January 10, 2008 Office Action issued in connection with U.S. Serial No. 10/799,264 **(Exhibit 5)**; and

6. October 17, 2008 Final Office Action issued in connection with U.S. Serial No. 10/799,264 **(Exhibit 6)**.

This Supplemental Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(c)(2). Accordingly, applicant encloses a check in the amount of ONE HUNDRED AND EIGHTY DOLLARS ($180.00) for filing this Supplemental Information Disclosure Statement.

The Examiner is respectfully requested to make the listed items of record in the present application by initialing and returning a copy of the enclosed Form PTO-1449 (Substitute).

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed Information Disclosure Statement fee of $180.00, is deemed necessary in connection with the filing of this Amendment and Supplemental Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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Gary J. Gershik 9/2/09

Gary J. Gershik Date
Reg. No. 39,992

1: Am J Surg. 1976 Jun;131(6):722-4.

Complete enteral support of thermally injured patients.

Larkin JM, Moylan JA.

Total enteric nutritional support of thermally injured patients is a safe, effective means of providing adequate caloric and nitrogen requirements and avoiding the usual weight loss associated with burns. Protein and vitamin supplements and tube feeding, when indicated, are necessary adjuncts to the standard high protein, high calorie hospital diet. A team approach, consisting of physicians, nurses, dietitians, and patients, and careful daily monitoring of all parameters is essential to the success of this method.

PMID: 820213 [PubMed - indexed for MEDLINE]

Related Links

Oral hyperalimentation in the nutritional management of burned patients. [S Afr Med J. 1985] PMID:3922066

Nutritional evaluation of a blenderized diet in five major burn patients. [Am J Surg. 1982] PMID:6816081

Nutrition guidelines for burned patients. [J Am Diet Assoc. 1986] PMID:3084608

Nutrition in the severely burned child. [Prog Pediatr Surg. 1981] PMID:6784187

Actual burn nutrition care practices. A national survey (Part II). [J Burn Care Rehabil. 1989] PMID:2496131

Applicant: Don Fishbein
Serial No.: 10/799,197
Filed: March 12, 2004
Exhibit A

J Surg Clin North Am. 1978 Dec;58(6):1151-6.

Nutritional support of the burned patient.

Curreri PW, Luterman A.

Patients with major thermal injury exhibit hypermetabolism as a result of neurohormonal alterations. Thus caloric requirements are exaggerated. Failure to provide supranormal caloric intake by both enteral and parenteral routes is associated with pronounced weight loss, delayed wound healing, decreased host resistance, and cellular dysfunction. Special dietary programs delivered early in the course of treatment must be utilized to prevent these complications of acute postburn malnutrition.

PMID: 104400 [PubMed - indexed for MEDLINE]

Related Links

Parenteral and enteral nutrition of the thermally injured patient. [Ann Chir Gynaecol. 1980] PMID:6781401

[Gastrointestinal dysfunction and peroral nutrition after severe burns] [Zhonghua Zheng Xing Shao Shang Wai Ke Za Zhi. 1992] PMID:1304954

[Problems in parenteral nutrition and metabolic support for burned patients] [Zhonghua Zheng Xing Shao Shang Wai Ke Za Zhi. 1992] PMID:1304953

Early enteral feeding of a severely burned pediatric patient. [J Burn Care Rehabil. 1994] PMID:8056824

Burn care. Metabolic alterations and nutritional management. [AACN Clin Issues Crit Care Nurs. 1993] PMID:8489885

Applicant: Don Fishbein
Serial No.: 10/799,197
Filed: March 12, 2004
Exhibit B